K130553

JUL 3 2013

510(k) Summary

This summary of information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

510(k) owner's name: Pharmaplast S.A.E.

Address: Amria Free Zone, 23512, Alexandria, Egypt

Phone and fax numbers: +203-450-0264, Fax +203-450-0263

Contact person: Mamdouh Atteia

Summary Date: 27 September 2012

Trade or proprietary name of the device: AbsoClear®

Classification Name: Dressings, Wound and Burn, Occlusive [no drug or biologic]

Product Code: FRO

Classification: Unclassified; 510[k] required

Legally marketed device to which equivalence is claimed: 3M Tegaderm™ Transparent Film Dressing; K973063

Device Description

The AbsoClear product family is a series of single-use, sterile transparent synthetic wound dressings made of absorbent acrylic polymers. The dressings maintain a moist wound environment, which has been shown to be conducive to wound healing, but that also can also absorb wound exudate. Full transparency allows monitoring wound healing stages without removal of the dressing. The sterile dressings are supplied singly in sealed trilaminate pouches and are sterilized by gamma irradiation.

Intended Use

Sterile, single-use dressings for management of pressure ulcers, 1st and 2nd degree bums, skin tears, abrasions, or irritated skin and surgical incisions and graft donor sites.

Comparison to predicate device

Summary Comparison Table of New Device to Predicate Device

Parameter	Device	Predicate Device
Device Name	AbsoClear Gel AbsoClear Gel Comfort	Tegaderm Transparent Film Dressing
Manufacturer	Pharmaplast S.A.E.	3M
510[k] #	K130553	K811291, K812678, K852750, K901845, K932422, and K973036
Class	Unclassified	Same
21 CFR number/category	NA	Same
Code	FRO; unclassified	Same
Product Type	Dressings, Wound and Burn, Occlusive	Same
Description	Transparent, nonresorbable, sterile dressing	Same

Parameter	Device	Predicate Device
Intended Use	For management of pressure ulcers, 1st and 2nd degree bums, skin tears, abrasions, or irritated skin and surgical incisions and graft donor sites.	To cover and protect catheter sites and wounds, to maintain a moist environment for wound healing or to facilitate autolytic debridement, as a secondary dressing, as a protective cover over at-risk skin, to secure devices to the skin, to cover first and second degree burns, and as a protective eye covering. Do not use the dressing as a replacement for sutures and other primary wound closure methods.
Style	Flat; adhesive edge on some models	Flat; adhesive edge
Components	Polyurethane film backing laminated with a synthetic acrylate dressing	Same
Additive	No drug or biologic agent	Same
End User	Healthcare professionals and consumers	Same
Frequency of Use	Single-use only	Same
Mode of Action	Provides a barrier to liquids and contaminants, supports a moist wound environment, and allows the exchange of gases such as oxygen and water vapor	Same
Sterility	SAL 10e-6; gamma irradiation; ISO 11137	Same

Bench Testing

All acceptance criteria for the following were met in GLP testing of each lot of AbsoClear product: absorption capacity, sterility, package seal strength and seal integrity. For products that include adhesive borders, routine acceptance testing includes coat weight, peel adhesion, and MVTR.

Sterilization

The gamma sterilization process was validated per ISO 11137 to a Sterility Assurance Level of 10^{-6}. Bioburden and pyrogenicity testing were done as part of this process and all acceptance criteria were met.

Shelf-life

Testing was done per multiple standards on the following to ensure that the product and packaging met all specifications after storage at 40°C for twelve months plus real time stability at 25°C for three years: peel adhesion; moisture vapor transmission rate; absorption capacity; sterility; packaging seal strength; packaging seal integrity. Shelf-life of the product is validated to three years.

Biocompatibility

Per ISO 10993-1:2009, AbsoClear is categorized as surface-contacting device that comes in contact with breached or compromised surfaces and has a possible exposure time of >24 hr. but not to exceed 30 days. According to this categorization the following biocompatibility tests were performed with the finished packaged, sterilized product: cytotoxicity [ISO 10993-5]; sensitization [ISO 10993-10]; and intracutaneous reactivity [ISO 10993-10]. Tests were done by an accredited testing laboratory and the product met all acceptance criteria.

Clinical Studies

All materials used in these products have been in use for these indications for many years. Therefore, non-clinical data on the pharmacodynamics, pharmacokinetics as well as on the toxicity of the substance are available. Additional clinical testing was not required.

Device Comparison Statement

The Pharmaplast S.A.E. AbsoClear product line is biocompatible and has similar technological characteristics and materials as a previously cleared device and therefore raises no new no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

Pharmaplast S.A.E.
% Biotechnology Transfer, LLC
Ms. Cynthia Pritchard
1016 Tobiano Lane
Raleigh, North Carolina 27614

July 3, 2013

Re: K130553
Trade/Device Name: AbsoClear
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 27, 2013
Received: May 22, 2013

Dear Ms. Pritchard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Document Mail Center WO66-G609
Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Indications for Use

510(k) Number (if known): K130553

Device Name: AbsoClear Gel and AbsoClear Gel Comfort

Indications for Use:

Sterile, single-use dressings for management of pressure ulcers, 1st and 2nd degree bums, skin tears, abrasions, or irritated skin and surgical incisions and graft donor sites.

Prescription Use ___X___ and Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130553